REMARKS

Reconsideration and withdrawal of the rejections and objections set forth in the Office Action of June 30, 2005, is respectfully requested in view of the foregoing claim amendments and following remarks.

The Claim Amendments and Pending Claims

Independent claims 1, 8, and 14 are hereby amended so that the claims are limited to methods involving the administration of a composition comprising an effective amount of a growth hormone wherein the composition is free from other appetite suppressing agents, satiety-inducing agents, and anti-diabetic agents. Paragraphs 0019, 0026, and 0058-0059 of the application (paragraph numbers are provided with reference to the published version of the application – i.e., US Patent Publication No. 20050171003) provide support for these claim amendments. Applicants note that these cited paragraphs make clear, albeit by implication, that the methods of the invention may be practiced with *or without* such additional pharmacological agents. Independent claim 8 is further amended by limiting the method to the treatment of impaired appetite regulation in a mature mammal suffering from one of a number of specific disorders associated with such a condition. Support for this amendment can be found at, e.g., paragraph 0053 of the application. Accordingly, these claim amendments introduce no new matter.

Claims 7, 12-13, and 15-16 are hereby cancelled.

New independent claim 18 is directed to a method of suppressing appetite in a mature mammal by administering GLP-1 and a growth hormone to the mammal. Support for this claim can be found in the application and original claims. Amendments to claim 17 are likewise supported by the original disclosure. The amendments to these claims also add no new matter.

Claims 1-6, 8-11, 14, 17 and 18 are pending and at issue. Claims 1, 8, 14, 17, and 18 are independent claims.

The Claims Are Novel

The Office Action rejected claims 1-3, 5-9, and 11-17 under 35 USC § 102(e)[1] as allegedly anticipated by the disclosure of commonly assigned US Patent Publication No. 2002/0011071 (i.e., US Patent 6,458,924) (Knudsen et al.) (hereinafter, "the Knudsen application").

The Knudsen application describes various *derivatives* of GLP-1 and GLP-1 *analogs*. Such chemical entities are non-natural, and, more importantly, are not the same as "GLP-1" as defined in the subject application. Specifically, the subject application defines "GLP-1" with reference to M. D. Turton et al., Nature 379, 4 January 1996, pp. 69-72 (see paragraph 0059). The Turton paper describes GLP-1 as "glucagon-like peptide-1 (7-36) amide (GLP-1)." The application makes it clear that "GLP-1" is different from other "GLP-1 peptides" (GLP-1s), such as GLP-1(1-37) and GLP-1(1-45) (see, e.g., paragraphs 0026 and 0059).

The Office Action points out that the Knudsen application includes claims to pharmaceutical compositions comprising such GLP-1 derivatives, which act as anti-diabetic agents, in combination with growth hormone as an antiobesity agent.

Independent claims 1, 8, and 14, as amended, are directed to methods comprising administering a composition that includes an effective amount of a growth hormone but that is free of additional appetite suppressing agents, satiety-inducing agents, and anti-diabetic agents. As the Knudsen application is directed to combination therapies and compositions (when referencing growth hormone), this reference cannot be said to anticipate any of these claims. Nowhere does the Knudsen application teach or suggest the use of such a composition. Accordingly, the Knudsen application anticipates neither any of these claims nor any claims that depend from these claims. Independent claims 17 and 18 are directed to methods and compositions that comprise "GLP-1" and a growth hormone. As indicated above, the Knudsen application is directed to GLP-1 derivatives, not GLP-1. The Knudsen application does not describe a

[1] Applicants reserve their right to alternatively overcome the Knudsen reference by other means (e.g., "swearing behind") later in the prosecution of the subject application, should the need arise.

composition or method having the features of these claims. Accordingly, the Knudsen application also does not anticipate these claims.

The Claims Are Directed to Nonobvious Subject Matter

The Office Action rejected claims 1-17 under 35 USC § 103 as allegedly being unpatentable over the Knudsen application. Respectfully, such a rejection is in error. The Office Action indicates that the Knudsen application is only cited as prior art under Section 102(e). 35 USC § 103(c) specifies that subject matter developed by another, which qualifies as prior art only under Section 102(e) "shall not preclude patentability under this section [i.e., Section 103] where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person." At the time the invention disclosed in the subject application was made, both the inventors of it, and the inventors of the Knudsen application, were under an obligation to assign their rights to Novo Nordisk A/S. Accordingly, the Knudsen application is not properly citable as prior art against the subject application under 35 USC § 103.

The Office Action further rejected claims 1-17 as allegedly encompassing subject matter that would have been obvious over the teachings of US Patent 6,191,160 (Gao et al.) in view of the Knudsen application. With all due respect, there are several reasons why this rejection also is misplaced.

First, as indicated above, the Knudsen application is not properly citable under 35 USC § 103 against the subject application. Thus, to the extent that the rejection relies on this combination, the rejection must necessarily fail.

Secondly, amended independent claims 1, 8, and 14, as described above, are directed to methods comprising administering a composition comprising an effective amount of a growth hormone wherein the composition is free of additional appetite suppressing agents, satiety-inducing agents, and anti-diabetic agents. The Gao patent is directed to neuropeptide Y antagonists and only makes passing reference to combination of such molecules with other "anti-obesity agents" including "growth

hormone secretagogues" *or* "GLP-1 agonists."[2] Thus, even making the assumption that growth hormone secretagogues should be treated as equivalents of growth hormone peptides, a point not conceded by Applicants, the Gao patent still teaches away from the subject matter of these claims by teaching a combination therapy (i.e., a therapy that includes the neuropeptide Y antagonists).

Third, the Gao patent makes no explicit description of a combination of a growth hormone secretagogue and "GLP-1 agonist" and certainly provides no teaching that would enable one of ordinary skill in the art to use such a combination for suppressing appetite in a mature mammal. Therefore, even assuming that (1) a "growth hormone secretagogue" should be construed as an equivalent of a "growth hormone" and (2) that a "GLP-1 agonist" should be construed as an equivalent of "GLP-1", the Gao patent fails to disclose all of the elements of the claimed invention, and particularly in a manner that would enable one of ordinary skill in the art to arrive at it. Therefore, the Gao patent cannot be considered to appropriate support a *prima facie* obviousness rejection with respect to any of the present claims.

Double Patenting

The Office Action rejected claim 17 under the doctrine of obviousness-type double patenting in view of claims 1, 8, and 18 of US Patent 6,458,924 (the patent that arose from the Knudsen application, discussed above). For the reasons indicated above, Applicants submit that the double patenting rejection is in error. Specifically, the Knudsen patent is directed to derivatives of GLP-1, not GLP-1. Moreover, claim 18 is directed generically to an anti-obesity agent, rather than a growth hormone.

Nonetheless, if the Office maintains the double patenting rejection, Applicants will either cancel claims 17 and 18 or enter a terminal disclaimer in the subject application upon a determination that these claims are otherwise allowable.

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[2] Applicants note that the Gao patent does not in any way suggest that "GLP-1 agonists" should be interpreted as being equivalent to GLP-1 peptides, making the appropriateness of a Section 103 rejection based on this reference more suspect.

One of Ordinary Skill is Enabled to Practice the Claimed Invention

The Office Action rejected claims 8-13 under 35 USC § 112, first paragraph, as allegedly encompassing subject matter that is beyond the enabling disclosure of the subject application when combined with knowledge in the art. Specifically, the Office Action objected to the inclusion of "prevention" of impairment of appetite in these claims. While not conceding the point, or agreeing with the statements made in the Office Action, Applicants have by the present amendments removed the "prevention" language from these claims (in accordance with the Examiner's suggestion – see page 8 of the Office Action), thereby obviating the basis for the enablement rejection.

The Claims Are Sufficiently Definite

The Office Action further rejected claims 1-17 under 35 USC § 112, 2nd paragraph, as allegedly being indefinite.

The Office Action objected to the inclusion of the phrase "mammal" in claim 1. The amendment to claim 1 removes this word from the claim, addressing this ground of rejection.

The Office Action objected to the use of the terms "disease" and "disorder" in claim 8. The terms have been removed from the claim, thereby obviating this basis for rejection.

The Office Action also cited the use of the phrase "appetite suppression" in claim 1 and the use of similar language throughout the claims as a basis for rejecting the claims as allegedly indefinite. Respectfully, one of ordinary skill in the art would *reasonably* understand the scope of claims including such phrases given the disclosure of the subject application particularly when read in view of the understanding of the phrase in the relevant art.

In rejecting a claim under the second paragraph of 35 USC 112, it is incumbent *on the examiner* to establish that one of ordinary skill in the pertinent art, when reading the claims in light of the supporting specification, would not have been able to ascertain with a *reasonable degree of precision* and particularity the particular area set out and circumscribed by the claims. *Ex parte Wu,* 10 USPQ2d

2031, 2033 (BPAI 1989). Breadth of a claim is not to be equated with indefiniteness. See, e.g., *In re Miller,* 441 F.2d 689, 169 U.S.P.Q. 597 (CCPA 1971).

The Court of Appeals for the Federal Circuit has twice recently analyzed the definiteness requirement of Section 112, second paragraph.

In the first case, the Court explained that "only claims 'not amenable to construction' or that are 'insolubly ambiguous' are indefinite." *Datamize, LLC v. Plumtree Software, Inc.,* 2005 U.S. App. LEXIS 16176, *11 (Fed. Cir. 2005 (August 5)). The Court further explained, "the definiteness of claim terms depends on whether those terms can be given any reasonable meaning." *Id.* "If the meaning of the claim is discernible, even though the task may be formidable and the conclusion may be one over which reasonable persons will disagree," the Court stated, "we have held the claim sufficiently clear..." *Id.*

In the other recent case analyzing the definiteness requirement, the Federal Circuit explained that "the statute is satisfied if a person skilled in the filed of the invention would reasonably understand the claim when read in the context of the specification." *Marley Mouldings, Ltd. V. Mikron Indus., Inc.,* 2005 U.S. App. LEXIS 16477 *7-8 (Fed. Cir. 2005 (August 8)). The *Marley Mouldings* decision further states that "the definiteness requirement set forth in § 112 ¶2 'focuses on whether those skilled in the art would understand the scope of the claim when the claim is read in light of the rest of the specification.'" *Id.* "If the claims 'reasonably apprise those skilled in the art of the scope of the invention,' §112 demands no more," the decision clarifies. *Id.*

The subject application defines the scope of appetite suppression (see paragraph 0039) ("the term 'appetite suppression' is intended to mean any activity or function which causes a decrease in food intake or consumption e.g. by inducing a feeling of satiety or by inhibiting or down-regulating the sensation of hunger"). The measurement of satiety, the regulation of hunger sensations, and the measurement of food intake are all benchmarks that are well known to the ordinarily skilled artisan. As such, the term should be considered sufficiently definite on its face.

Additionally, the definition of "appetite suppression" provided by the subject application is consistent with the general understanding of this phrase, which is widely used in the relevant art (and accordingly would be reasonably understood by those working in relevant fields). Indeed, numerous US patents have issued that include the phrase "appetite suppression" or similar phases in the claims and/or title, most of which contain no further definition or at least not more explicit definition of the phrase (see, e.g., US Patent 6,905,702 ("Methods for regulating blood glucose and appetite suppression in type 2 diabetics"); US Patent 6,884,454 ("Appetite suppressing diet bar"); US Patent 6,610,277 ("Appetite suppressant toothpaste"); US Patent 6,534,487 ("Methods for suppressing appetite and enhancing exercise and recovery"); US Patent 6,521,266 ("Composition for growth hormone production and release, appetite suppression, and methods related thereto"); US Patent 6,376,657 ("Pharmaceutical compositions having appetite suppressant activity"); US Patent 6,025,363 ("Composition for suppressing appetite"); US Patent 5,985,282 ("Herbal appetite suppressant and weight loss composition"); US Patent 5,912,229 ("Use of a pharmaceutical composition comprising an appetite-suppressing peptide"); US Patent 5,783,603 ("Potassium hydroxycitrate for the suppression of appetite and induction of weight loss"); US Patent 5,688,784 ("Method of suppressing appetite with vanadium complexes"); US Patent 5,169,852 ("Method of suppressing appetite by administration of tetrahydro-beta-carboline derivatives"); and US Patent 4,459,298 ("Method of suppressing appetite")). These exemplary US patents evidence that the phrase "appetite suppression" is well understood in the art. The common usage of the phrase is also reflected in relevant scientific literature (see, e.g., Halford et al., "Pharmacology of appetite suppression," Prog Drug Res. 2000;54:25-58; Bergstrom J., "Mechanisms of uremic suppression of appetite," J Ren Nutr. 1999 Jul;9(3):129-32; Curzon et al., "Appetite suppression by commonly used drugs depends on 5-HT receptors but not on 5-HT availability," Trends Pharmacol Sci. 1997 Jan;18(1):21-5; King et al., "Exercise-induced suppression of appetite: effects on food intake and implications for energy balance," Eur J Clin Nutr. 1994 Oct;48(10):715-24; and Blundell J.,

"Pharmacological approaches to appetite suppression," Trends Pharmacol Sci. 1991 Apr;12(4):147-57). Given the widespread use of phrases such as "appetite suppression" in the art, Applicants respectfully submit that the ordinarily skilled person would be able to *reasonably* determine the scope of the present claims despite inclusion of this phrase.

The Office Action sets forth no other reason why the claims were rejected as indefinite.

Conclusion

In view of the above, Applicant(s) respectfully submit that the application is now in condition for allowance and issue and request early action to that end. The Commissioner is hereby authorized to charge any fees in connection with this application and to credit any overpayments to Deposit Account No. 14-1447. The Examiner is invited to contact the undersigned by telephone if there are any questions concerning this amendment or application.

Respectfully submitted,

Date: September 22, 2005

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